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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------------|
| 09/740,821 | 12/21/2000 | Daniel C. Carter | P06652US01/BAS | 6567 |
| 881 7590 01/11/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314 | | | EXAMINER LIU, SAMUEL W | |
| | | | ART UNIT 1656 | PAPER NUMBER |
| | | | MAIL DATE 01/11/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/740,821 | Applicant(s) CARTER, DANIEL C. | |
| | Examiner Samuel W. Liu | Art Unit 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 52-57 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 and 52-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DTAILED ACTION

Status of claims

Claims 50 and 52-57 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 10/31/07 has been entered.

The amendment filed 10/31/07 which cancels claims 1-49 and 51, amends claims 50-52-54 and adds claim 57 has been entered. New claim 57 is drawn into the elected invention. Thus, claims 50 and 52-57 are examined in this Office action.

Withdrawal of claim rejection

The rejection under 35 USC 103(a) of claims 50 and 52-56 by Mausner, J. and Miller, D. G. is now withdrawn in light of that the isolated non-recombinant human serum albumin is obvious variation of the recombinantly produced human albumin (see the Office action mailed 3/28/07 and below).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites "consisting essentially of ... albumin and a cleansing agent, vehicle, carrier or excipient"; the recitation is unclear whether or not vehicle, carrier or excipient is the cleansing agent. Claims 52-57 which depend from claims 50 are also rejected because these claims do not cure the defect of claim 50.

* Examiner note: there is no response to the rejection under 35 USC 112, second paragraph addressed in the response filed 10/31/07.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

• Claims 50 and 52-56 remain and claim 57 is rejected under 35 U.S.C. 102(b) as anticipated by Mausner, J. (US Pat. No. 5254331).

In patent claim 6 and Table 1, Mausner teaches a skin cream composition comprising human serum albumin (item *i*), and steareth-21 which is a surfactant and cleansing agent for cosmetic use (see "*Discussion of art*" [3]) and which accounts for ~ 1.3%-1.7% of the composition. Water or glycogen set forth in Table 1 and claim 6 is considered to be equivalent to instant "carrier". Since "soap" is a cleansing agent (see "*Discussion of art*" [2]), and since a

recombinantly produced albumin and an isolated/non-recombinantly produced albumin are considered to be structurally/functionally identical as the same protein can be produced by different means, Mausner inherently teaches the composition of instant claims 50 and 57.

Also, Mausner teaches that the protein complex comprises about 28% serum protein (col. 7, line 3), wherein the protein complex comprises ~6.9% of the skin cream composition; thus, the human serum albumin is 1.9% (calculation: $28\% \times 6.9\% = 1.9\%$) of said composition. 1.9% is 1.9 g /100g, approximately equivalent to 1.9g/100 ml, i.e., 19 mg/ml. This anticipates instant claims 52-53 and 55-56.

- (New) Claims 50, 52, 54-55 and 57 are rejected under 35 U.S.C. 102(b) as anticipated by Beaulieu A. (US Pat. No. 5641483).

In patent claims 17-18 and 23, Beaulieu teaches a formulation comprising (i) "cetech-20" (claim 18) which is a cleansing agent (see "*Discussion of art*" [1]), and (ii) albumin which acts as a stabilizer (claims 22-23). Beaulieu further teaches that said albumin is preferably human albumin (col. 5, lines 26-27). Because a recombinantly produced albumin and an isolated human albumin/non-recombinantly produced are considered to be structurally/functionally identical as the same protein can be produced by different means, and because "soap" is a cleansing agent (see "*Discussion of art*" [2]) and "ceteth-20" (polyoxyethylene-(20)-cetyl alcohol, a hydrophilic molecule) is in a liquid form; this is due to said formulation containing water (see claim 18, and col. 5, lines 1-2) wherein water is considered to be equivalent to instant "carrier", Beaulieu inherently teaches the composition of instant claims 50, 54 and 57.

In patent claim 24, Beaulieu further teaches that the albumin is present about 0.10% by

weight that is 0.1 g/100 ml, i.e., 1 mg/ml, which anticipates claims 52 and 55.

* Examiner note: The preamble "cleansing" in claims 50 and 52-37 is considered to refer to an intended use of the claimed "composition", which has little patentable weight because components/ingredients of said composition will not be altered/modified by how to use the composition thereof.

Applicants' Response to the rejection under USC 35 102(b) by Mausner

At page 2, the response filed 10/31/07 submits that Mausner patent (US Pat. No. 5254331) does not teach use of the recombinant human serum albumin (HSA) in any cleansing composition (page 2), and that, although the Mausner's composition is a cosmetic composition, the cosmetic composition is not a cleansing composition (page 2, last line to page 3, 1st paragraph), and the Mausner's composition is used to antiwrinkle. Thus, the response asserts that Mausner teaches away from the instant invention (pages 3-4). Also, the response argues that the steareth-21 is an emulsifier used in many products and is not cleansing agent. By discussing US Pat. NOs. 5968490, 5693670 and 6548074 (page 5, 1st paragraph), the response asserts that because steareth-21 is used in antiperspirant composition (5968490), used in sunscreen composition (5693670), and used in an cosmetic composition, e.g., elastomer emulsion (6548074), and because none of compositions discussed is the cleansing composition, surfactant steareth-21 is not considered to act as cleansing agent. The response therefore requests withdrawal of the rejection.

The applicant's arguments are found unpersuasive because the reasons discussed in the above rejection and reasons below. The "cleansing" before the claimed "composition" is considered to be an intended use which has little patentable weight since the structural property of the composition thereof will not be altered by how to use the composition thereof. As discussed above, the recombinantly produced HSA and a non-recombinantly produced/isolated HSA should have the same structural/functional properties because the same protein can be produced by different means. Thus, the argument with regard to "Mausner's composition is used to antiwrinkle" is not persuasive.

Stearth-21 is a cleansing agent (see the above discussion) presented in significant amount ~1.7 g/100 ml, i.e., 17 mg/ml (see Table 1 of 5254331), suggesting that the composition comprising this "cleansing agent" necessarily possesses "cleansing" property. Because soap is a cleansing agent (see "*Discussion of art*"[3]), water-dissolved stearth-21 (see Table 1 and claim 6 of 5254331) has inherent property of the liquid soap. The different uses of stearth-21 discussed by the response referring to 5968490, 5693670 and 6548074 will not and cannot change or modify its cleansing property thereof. Thus, the Mausner composition teaches instant invention, and therefore, the rejection is proper and maintained.

Conclusion

No claims are allowed.

Discussion of the art

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

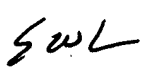
[1] Net Wellness (2007, updated) *Common Ingredients in Skin Care Products*,
“<http://www.netwellness.org/healthtopics/skincare/faq4.cfm>, pages 1-7) teaches that ceteth-20,
i.e., polyoxyethylene-(20)-cetyl alcohol, is a cleansing agent (see page 2).

[2] Dictionary (2007, updated) “Soap”, <http://www.thefreedictionary.com/soap>, page 1)
teach that soap is type of cleansing agent.

[3] Cosmetics INFO (2007, updated) Steareth-21, http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=1650, pages 1-2) teaches that steareth-21 is a cleansing
agent and surfactant (see page 2).

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to
reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher
Low, can be reached on 703 308-2923. The fax phone number for the organization where this
application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-
9307 (after final). Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the receptionist whose telephone number is 703 305-4700.


Samuel Wei Liu, Ph.D.
Patent Examiner, Art Unit 1656
January 3, 2008


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER